Vigilância Sanitária em Debate
ISSN: 2317-269X
INCQS-FIOCRUZ

Abud, Carol de Oliveira; Souza, Luciano Pereira de
A vacinação contra a COVID-19 pode ser compulsória no Brasil? A questão jurídica e a disputa política
Vigilância Sanitária em Debate, vol. 9, no. 4, 2021, October-, pp. 4-15
INCQS-FIOCRUZ

DOI: https://doi.org/10.22239/2317-269x.01881

Available in: https://www.redalyc.org/articulo.oa?id=570572979002

ARTICLE
https://doi.org/10.22239/2317-269x.01856

Can the vaccination against COVID-19 be compulsory in Brazil? The legal issue and political dispute

A vacinação contra a COVID-19 pode ser compulsória no Brasil? A questão jurídica e a disputa política

Carol de Oliveira Abud*

Luciano Pereira de Souza

Universidade Santa Cecília (Unisanta), Santos, SP, Brasil

* **E-mail:** abudcarol@hotmail.com

Received: 08 Jan 2020
Approved: 19 Jul 2020

ABSTRACT

Introduction: The recent uproar around COVID-19 hangs over the rights and duties of the population regarding vaccination and mass immunization. The exercise of individual freedom and the possible imposition of a measure that makes vaccination compulsory may be the focus of a political dispute around the adoption of scientific criteria for government decision-making, and with that, bring serious collective consequences in relation to the spread and the lack of control of the disease. **Objective:** To study whether compulsory vaccination against COVID-19, once instituted by law or normative act, will have a legal basis in view of fundamental rights and analyze whether the political dispute around the vaccine may be influencing its regulation. **Method:** Exploratory and descriptive study developed through documentary and bibliographic research, collection of texts from the World Health Organization, Ministry of Health, federal government and the state of São Paulo, analysis of national legislation and recent decisions by the Supreme Court. **Results:** It was observed that it is possible to establish compulsory vaccination in Brazil, ensuring fundamental rights; however, political issues are influencing decision-making based on technical-scientific criteria for health surveillance. **Conclusions:** The restriction of individual freedom finds support in the search for health in the collective interest, as long as it does not go beyond the limits of the physical integrity of the citizen and human dignity, the use of physical coercion being prohibited. The political dispute led by some public agents may have caused delays and setbacks in the vaccination of the Brazilian population, an effective way to control the pandemic.

KEYWORDS: Right to Health; Coronavirus Infections; Public Health; Immunization Programs; Vaccination Refusal

RESUMO

Introdução: A recente celeuma em torno da COVID-19 paira sobre os direitos e deveres da população frente à vacinação e a imunização em massa. O exercício da liberdade individual e a eventual imposição de medida que torna compulsória a vacinação podem estar no foco de uma disputa política em torno da adoção de critérios científicos para a tomada de decisões governamentais que poderão trazer sérias consequências coletivas em relação à propagação e ao descontrole da doença. **Objetivo:** Estudar se a vacinação compulsória contra a COVID-19, uma vez instituída por lei ou ato normativo, terá fundamentação jurídica em face dos direitos fundamentais e analisar se a disputa política em torno da vacina pode estar influenciando a sua normatização. **Método:** Estudo exploratório e descritivo elaborado por meio de pesquisa documental e bibliográfica, coleta de textos provenientes da Organização Mundial da Saúde, do Ministério da Saúde, do governo federal, do estado de São Paulo, da análise da legislação pátria e de decisões recentes do Supremo Tribunal Federal. **Resultados:** Observou-se que é possível estabelecer a vacinação compulsória no Brasil assegurando os direitos fundamentais, entretanto, questões políticas estão influenciando a tomada de decisões pautadas por critérios técnico-científicos de Vigilância Sanitária. **Conclusões:** A restrição da liberdade

individual encontra amparo no fundamento de busca pela saúde de interesse coletivo, desde que não extrapole os limites da integridade física do cidadão e da dignidade humana, vedado o uso da coerção física. A disputa política encabeçada por alguns agentes públicos pode ter acarretado atrasos e retrocessos na imunização vacinal da população brasileira, forma eficaz de controle da pandemia.

PALAVRAS-CHAVE: Direito à Saúde; Infecções por Coronavírus; Saúde Pública; Programas de Imunização; Recusa de Vacinação

INTRODUCTION

The World Health Organization (WHO), faced with the emergence of the disease caused by the new coronavirus, coronavirus disease or COVID-19, reported at the end of 2019[1], declared, on January 30, 2020, Public Health Emergency of International Concern (PHEIC)[2], due to the outbreak of this disease in several countries. A few weeks later, on March 11, 2020, the WHO declared the disease a pandemic situation[3]. Thus, a global battle against the disease began, as the virus began to circulate on a worldwide scale.

According to the Coronavirus Resource Center at Johns Hopkins University, from the beginning of reported cases until January 7, 2021, the date on which the data for this work was collected, the world has accumulated a total of 87,434,105 confirmed COVID-19 cases, of which 1,889,952 people died[4].

In Brazil, the figures officially released by the Ministry of Health until the same date totaled 7,873,830 COVID-19 cases, with 198,974 people dying from the disease[4,5].

It can be deduced from these data that Brazil accounts for 10.52% of deaths caused by COVID-19 in the world, while its population represents only 2.71% of the world population[6,7].

During these months, since the installation of the pandemic state until today, the international and national scientific community began to seek, through studies, a way to contain the disease. Initially, non-pharmacological measures were adopted worldwide, with guidance from the WHO itself. Measures such as: social distancing, constant hand hygiene with alcohol gel or soap, and use of homemade or medicinal face mask were the correct prophylactic decisions so far[8].

Despite the accurate adoption of these prophylaxis measures, what is expected is the discovery of one (or several) effective and safe immunizing vaccines.

Scientists pursued this goal and, in record time, – so considered by science – reached the final stages of testing vaccines[9], some of which have already achieved efficacy of up to 97%.

Vaccines from various laboratories and countries, when approved by the national health control of each country, are introduced into the respective communities, which has already occurred in at least 47 countries (as of January 8, 2021, time of submission of this article). For this, however, it is necessary an effective planning of vaccination of the population. Each country should guide the immunization of its population through this plan[10].

In Brazil, two large and renowned research centers that for years have been producing vaccines for use by the Brazilian National Immunization Program (PNI) are participating in the vaccine search process: the Instituto Butantan, in São Paulo, in partnership with the Sinovac Life Science laboratory, with the Coronavac vaccine[11], and the Oswaldo Cruz Foundation (Fiocruz), in Rio de Janeiro, which works in partnership with the laboratory AstraZeneca/University of Oxford[12], with the CHADOX1 NCOV-19 vaccine, and which participates in the coordination of clinical trials of several vaccines, including Coronavac[13].

By the end of the research, four vaccines were officially being tested in Brazil: the two mentioned above, with technology transfer, the vaccine from the Pfizer-Wyeth laboratory (BNT162 vaccine) and the one from the Janssen-Cilag laboratory (AD26.COV2.S vaccine), without local technology transfer[14]. At any time, other new vaccines may be submitted to the Brazilian National Health Surveillance Agency (Anvisa).

Once the testing stage by the laboratories has been completed and all the required protocol has been completed, with the authorization of the regulatory agency (Anvisa), the immunizers will be able to be distributed and even marketed in Brazil. However, for the application of the immunizer in the population to occur free of charge and guaranteed by the Union through the Unified Health System (SUS), there is a need for a government strategy, in the form of an infra-legal norm and planning.

The present study aims to analyze the legal feasibility of compulsory vaccination within the scope of the necessary vaccine planning against COVID-19 in Brazil and to assess whether the political dispute or politicization around the vaccine may be influencing its regulation, since attributing a political (ideological and eventually electoral) character to the issue of compulsory immunization can distance the State from making decisions based on technical-scientific criteria of Sanitary Surveillance.

METHOD

To achieve the objectives, we carried out exploratory and descriptive research through the collection of texts from the WHO, the Ministry of Health, the federal government, the state of São Paulo, national legislation, and recent decisions of the Supreme Federal Court (STF).

For the normative analysis, we adopted the technical-legal method, based on the interpretation of the content of legal norms and other forms of expression of law, including and

especially the recent decisions of the STF in Direct Actions of Unconstitutionality (ADI nº 6.586 and ADI nº 6.587) and in the Extraordinary Appeal with Interlocutory Appeal (ARE nº 1267879 RG), which deal with mandatory vaccination against COVID-19 and the mandatory vaccine immunization of children and adolescents in accordance with the PNI.

We described the state actions at the federal level and the regulatory frameworks that led to the provision of compulsory vaccination as a measure to combat COVID-19, starting from the timeline of the declaration of the state of PHEIC by the WHO.

We examined the current PNI and made a brief comparison with the vaccination plan presented in the influenza A (H1N1) virus pandemic to deduce the need for logistical planning and inclusion of planning in the national vaccination policy, considering the severity of the disease and the risk of propagation.

We examined the International Health Regulations (IHR) and their implications for WHO member countries, which aim to prevent the spread and control the disease, based on the principles of human rights and individual freedoms.

We considered the main constitutional aspects of the application of the technique of balancing or proportionality judgment on compulsory vaccination as a measure that affects individual freedom of self-determination, based on individual rights and collective rights in the face of the pandemic characterization of the disease. We outlined the necessary measures regarding individual and collective health in the sanitary law, paying attention to human rights and the impacts they may cause to the community.

We evaluated possible influences of a political nature, guided by ideological convictions, since they were formed without a basis in scientific evidence, in the definition by the federal government and other federative entities regarding the compulsory or non-compulsory character of vaccine immunization against COVID-19.

Finally, we observed individual and collective rights and drew a parallel with the vaccine revolt to establish its link in relation to the political position in the current scenario of experienced polarization, suggesting the consequences arising from the hesitation to vaccinate.

The work does not propose to make a bioethical analysis of vaccine immunization, nor does it propose to discuss the cultural issue involved in the so-called anti-vaccine movement.

RESULTS AND DISCUSSION

With the declaration of the situation of PHEIC[2] by the WHO, the RSI[15] started to demand from the signatory countries the provision of information, the permanent assessment of risks and the notification to WHO of COVID-19 cases.

The IHR is an international legal instrument that has the accession of 194 countries (member states of the WHO), established with the purpose of helping the international community to prevent and respond to serious public health risks that have the potential to cross borders.

The IHR also requires participating countries to develop up-to-date and state-of-the-art surveillance and response capabilities, structures, and services for public health events.

Brazil is one of the WHO member countries and approved[16] the proposed IHR at the 58th WHO General Assembly, through Legislative Decree nº 395, of July 9, 2009.

When the WHO declared the PHEIH[2] on January 30, 2020, member countries were notified to take the necessary measures and adaptations for the health risk that could arise as a consequence of the new coronavirus. On the same date, Brazil responded to the WHO's call and, through Decree No. 10.212, of January 30, 2020, enacted the revision of the IHR text[17].

On February 3, 2020, the Ministry of Health, under the command of Minister Luiz Henrique Mandetta, in compliance with the recently enacted Decree and aware of the gap in the legislation in force at the time, promptly prepared the draft law on measures to face the PHEIC arising from the coronavirus[18]. The document was sent for presidential consideration and later became Bill No. 23/2020[19,20].

On February 6, 2020, the Bill was approved by the National Congress as a matter of urgency[20] and converted into Law No 13.979, which provides for measures to combat the PHEIC resulting from the coronavirus responsible for the 2019 outbreak[21]. It is possible to observe until then that the Ministry of Health started to act even before the WHO declared the pandemic state, from the recognition of the outbreak of the disease.

Federal Law No. 13,979/2020, with its respective amendments and additions, establishes that, in order to combat the PHEIC, the authorities may adopt, within their competences, compulsory measures such as vaccination (in article 3, item III, d)[21]. It also establishes that such compulsory measures of article 3 will only be taken based on scientific evidence and analyzes of strategic health information and must be limited in time and space to the minimum necessary for the promotion and preservation of public health (article 3, §1). And it assures people affected by the measures full respect for the dignity, human rights, and fundamental freedoms of people (article 3, §2, III), as recommended by article 3 of the IHR[15].

The IHR's principles are respect for the dignity, human rights, and fundamental freedoms of people, in compliance with the Charter of the United Nations and the Constitution of the World Health Organization (Article 3). The document sets as a goal the universal protection of all peoples of the world against the international spread of diseases. Finally, the article also clarifies that member states have the sovereign right to legislate and implement legislation in order to fulfill their own health policies[15].

The federal government, until mid-April 2020, under the guidance of the Ministry of Health, took quick decisions at the

beginning and even before the pandemic was declared, acting on the basis of scientific evidence. However, in the midst of a critical moment of the disease (in April 2020), doctor Luiz Henrique Mandetta was dismissed from the post of minister[22], and doctor Nelson Teich was appointed to the Ministry of Health[23]. A month after his appointment and with cases of deaths and infections in full ascendancy, the minister asked for his resignation[24] and, after a period without a minister in charge of the Ministry of Health, Army General Eduardo Pazzuello took over as interim (in June 2020)[25]. The minister was officially appointed only in September 14[26] and, until the date of writing of this article, remained in office.

Since this latest exchange of ministers, the Ministry of Health's information system on COVID-19 numbers has undergone a drastic modification. Information transparency was no longer as clear and actions were not as fast as they were initially[27,28,29].

Faced with this, and with no manifestation from the federal government on the strategy and planning of future vaccination, the Federal Court of Accounts (TCU), based on the understanding that the vaccination plan is a mandatory measure of commitment by Brazil, recommended to the Civil House of the Presidency (together with the Ministry of Health) to prepare an immunization plan for Brazil[30].

The TCU's recommendation came in August 2020, through the judgment of the rapporteur minister Vital do Rêgo (Judgment nº 2.092/2020), with the objective of evaluating and monitoring the governance (including and mainly in the planning of expenses for the production and acquisition of future vaccines and other inputs)[30] during the fight against COVID-19. In November 2020, the federal government appealed the TCU's decision.

At the same time, in the STF, two ADIs with antagonistic positions on vaccination were distributed: No. 6,586 and No. 6,587, both reported by Minister Ricardo Lewandowski[31,32]. Number 6,587, seeking the recognition of states and municipalities to determine the compulsory vaccination of the population and the analysis of the competence of the authorities and states to take measures regarding vaccination and the other, seeking the declaration of unconstitutionality of the compulsory vaccination provided for in Law No. 13.979/2020. A third demand, through the Allegation of Violation of a Fundamental Precept (ADPF No. 754)[31,32,33], also by the same rapporteur, asks the federal government to present a vaccination plan to fight the disease and that it can be part of the PNI[34]. Other actions and other arguments were distributed throughout the month of November and part of December, some absorbed for the judgment of these, and others judged in a similar sense.

On November 24, 2020, the rapporteur minister, in his vote on ADPF nº 754, determined that the federal government submit, within 30 days, a detailed vaccination plan against the disease and that it updates the plan in question every 30 days, by the end of 2021, and submit the plan to the National Congress for inspection and control.

On December 12, 2020, the federal government presented a national vaccination plan[35] and, in view of that, the rapporteur minister of the STF requested clarification on the presented plan, notably in relation to "(...) forecast of the beginning and end of the National Plan for Operationalization of the Vaccination against COVID-19, including its different phases". Having provided the information in a petition filed on December 15, 2020, on the same day, Minister Lewandowski determined its wide dissemination and the scientification of the National Congress[31,32,33].

According to the information provided by the Minister of Health: "The Ministry of Health estimates that in a period of twelve months it will complete the vaccination of the general population, which will depend, at the same time, on the amount of immunobiological available for use, completing the vaccination plan in a total of approximately sixteen months" (document from the records of ADPF No. 754), noting that:

> to date, there is still no vaccine available for immediate use in the Brazilian market, which, of course, is a condition for the availability of the vaccine. Furthermore, the incorporation of a vaccine to the National Vaccination Calendar will depend on the approval of the immunobiological by the Brazilian National Health Surveillance Agency (Anvisa), through a regular or emergency submission process.

In other words, the Ministry established the deadline (time interval) to vaccinate the population, but it was not yet possible to specify the start date of vaccination (up to that moment)[35].

The process that seeks to judicially demand an immunization plan from the federal government is not the object of this research, but it should be noted that it is still ongoing and pending judgment (until the end of the research), and on December 29, an incidental provisional injunction was requested for "(...) that the Union (Federal Executive Branch – Ministry of Health) be determined to present weekly the evolution of negotiations for the acquisition of all available vaccines listed by the WHO, the first being within a maximum period of 48 hours"[31,32,33].

In relation to compulsory vaccination, object of the present work, on December 16, 2020, the vote of the rapporteur minister in the ADI was in favor of compulsory vaccination, clarifying that vaccinating or not vaccinating is not an option, admitting restrictions allowed in the Federal Constitution (CF) with joint interpretation with Law No. 13,979/2020. He affirmed in a vote that the competence of the states is concurrent with that of the Union to develop measures on vaccination.

After the judgments of the ADI and the Extraordinary Appeal (topic 1103 of General Repercussion - ARE 1267879 RG)[36], which are of interest to the present study, as they discuss the question formulated by the research, the following binding theses were established (which require compliance by all state bodies and persons in the national territory):

> (I) Compulsory vaccination does not mean forced vaccination, as the user's refusal is always permitted,

> although it may be implemented through indirect measures, which include, among others, the restriction on the exercise of certain activities or the frequency of certain places, provided that they are provided for by law, or arising from it, and (i) are based on scientific evidence and relevant strategic analysis, (ii) respect human dignity and the fundamental rights of people, (iv) meet the criteria of reasonableness and proportionality, and (v) vaccines are distributed universally and free of charge; and (II) such measures, with the limitations set out above, can be implemented both by the Union and by the States, Federal District, and Municipalities, respecting their respective spheres of competence.

This thesis was established in the judgment of ADI No. 6.587, which discussed the constitutionality of article 3, III, d, of Law No. 13.979/2020, which provides for mandatory vaccination. Through this decision, the STF, by majority, partially upheld the action to give the questioned legal text an interpretation in accordance with the CF, recognizing the admissibility of compulsory vaccination, within the limits and under the terms set by the judgment thesis reproduced above[32].

Likewise, in its final part, the thesis resolved the questioning of ADI No. 6.586 regarding the competence of the federative entity to establish the obligation of the vaccine, establishing that all entities of the federation can institute compulsory vaccination "respecting their respective spheres of competence"[31].

Finally, with respect to the claimed refusal of parents or guardians to promote the vaccination of their minor children[36], the following judgment thesis was established, serving the case as a leading case:

> It is constitutional the mandatory immunization by means of a vaccine that, registered with a Health Surveillance agency, (i) has been included in the National Immunization Program or (ii) has its mandatory application determined by law or (iii) is subject to determination by the Union, State, Federal District, or Municipality, based on medical-scientific consensus. In such cases, it is not a violation of the parents' or guardians' freedom of conscience and philosophical conviction, nor of family power.

Faced with the clash and judicial decisions, we approach the research problem in three topics: the first describes the conflict between fundamental rights resulting from the compulsory vaccination; the second describes the vaccination plan and the need for a previous strategy for the application of vaccines; and the third will deal with possible consequences of the political position regarding aspects involving the legality and compulsory nature of vaccination.

Compulsory vaccination: the conflict between the individual and the collective

In the legal field, in order to resolve existing relationships or conflicts between public health and human rights, it will be necessary to balance individual rights (individual freedom and self-determination) and collective rights (community responsibility and interest).

Is the debate that takes place between the individual and the collective, between restricting freedoms (ability to self-determine in the face of vaccination) and guaranteeing collective health (protecting everyone's health with vaccination) to be considered a conflict of opposing positions?

In order to resolve the issue, it is necessary to clarify that some situations are admitted to restrict rights, without, therefore, transgressing human rights. The search for the common good is one of the ways to restrict the ability to self-determine[37].

There is no denial about individual liberties. The philosopher Kant[38] considers that the person has a free capacity to act, to establish an end for themselves. This meaning derives from autonomy, from the capacity for self-determination, from the free manifestation of the will. And in this sense, the CF really guarantees the right to self-determination as fundamental. Individual freedom is an unparalleled human achievement. It has fundamental value as the achievement of individual rights and guarantees.

We cannot forget, however, that the same legal diploma guarantees other rights as fundamental – such as the right to health. When the precepts guaranteed by other rights come into conflict in the constitutional norm, it is undeniably necessary to balance them out, in order to establish an order to be respected for the solution of the concrete situation[39].

In an illustrative way, we can consider the situation of the individual who does not like to wear a protective face mask while walking on the beach or the public person who prefers to make his public appearances in contact with his admirers or co-religionists without the use of the mask, a current regulation that imposes the use of this protective equipment for such situations. In these cases, their individual freedom of self-determination is restricted in the face of the collective interest in health[40].

These situations are practical and everyday examples of the application of the proportionality criterion, which relies on techniques of adequacy, enforceability, and weighting to resolve conflicts between fundamental rights[41]. Proportionality will balance the conflict and give the fair measure and adequacy of the result[42]. The weighting will optimize the coexistence of these rights, in such a way that the State may limit (or restrict) one constitutional guarantee in favor of another.

Let us now imagine cases that involve risk to the health and physical integrity of an entire nation or the humanity. If, for the aforementioned cases, proportionality acts to weigh fundamental rights and principles, there is no need to be different in the matter of compulsory vaccination.

The declaration of a pandemic status of COVID-19 is clearly a situation that authorizes the restriction of the right to individual freedom when what is at risk is collective health, since when

we consider collective security and individual integrity, the right that protects everyone's health will prevail.

Citizens in their private sphere (in their family nucleus) are not obliged to wear protective face masks, but collectively they are, as the risk of contaminating themselves and others is greater when the prophylactic measure is not respected[40].

In vaccination, the motivation for mandatory vaccination is similar.

Getting vaccinated means reducing risks, since the production of antibodies will act against pathogens that cause infections. Vaccines are the main form of prevention against several diseases because they not only protect the individual who was immunized, but protect the entire community, because that individual, by not getting sick, also does not become a transmitter of the disease (COVID-19), transmitting it to other people. The more people who are immunized, the greater the chance of eradicating (or controlling) the disease[43]. There are specific studies on the subject that even establish percentages of vaccination of the population so that the effect of collective protection can be achieved.

The smaller the number of immunized people, the greater the chance that the disease will spread in the community. This statement is supported by the recent return of measles circulation. The drop in adherence to measles vaccination, which had been eradicated in Brazil since 1989, has been identified as responsible for the return of measles in several regions[44].

The restrictive measure of individual freedom to impose vaccination for the benefit of the community, found in this study, reiterates the antagonism between private autonomy and collective decision, legitimizing the State to equate the conflict, taking a measure that imposes compulsory vaccination against COVID-19

There is, however, a difference between the mandatory use of a face mask in situations provided for by law and the compulsory use of the vaccine. The vaccine, as safe as it may be, still represents a risk, and can generate adverse events after its application and this is precisely the issue (among others) that should be considered as an aspect to be monitored in the vaccination plan or in any standardization or ordinance.

Therefore, in order to make the sacrifice to the individual right as small as possible and to avoid reaching other rights, such as life and health, due to compulsory vaccination, it would be advisable to have, in the vaccination plan to be implemented, temporary monitoring and other forms of damage compensation[45].

Immunization plan against COVID-19

The way in which vaccination should be carried out at the national level is through the incorporation of the new technology in the PNI[46].

The vaccines applied in the population's routine are those included in the official vaccination calendar by the PNI – with current coverage of 19 immunizations and prevention of 20 diseases[46,47]. The PNI, which is a reference in public policy, was formulated in 1973, institutionalized in 1975, and linked to the Ministry of Health.

The planning and vaccination coverage offered by it have the continuous character of immunization and, precisely because of this, its success, whose public policy objective is not to exclude anyone from mass vaccination. Through this program, disease control in all age groups becomes possible.

The new vaccines that appear in the scientific scenario, after approval by Anvisa, are incorporated into the PNI[48].

In the current context, to adapt to the PNI, the federal government through the Ministry of Health must integrate efforts, support, and seek activities and proposals for technological innovation of future COVID-19 vaccines. More than that, it must formalize the planning and regulations that aim to integrate the vaccination of the disease, outline the target population and the stages and dates of vaccination. It must provide for the number of materials to be used, the doses of immunizing agents (considering the two complete doses per individual, if applicable), the estimated costs for acquisition involving all stages of vaccination. And finally, as Dalcomo[49] clarified, it must ensure that the vaccination against COVID-19 does not interfere and does not harm the official vaccination of the current calendar. It is therefore unacceptable that vaccination against COVID-19 uses material intended for other campaigns, causing damage to other vaccine coverage.

Yielding to judicial, political, and public pressure, on December 1, 2020, days after presenting the defense at the TCU challenging the ruling that recommended the preparation of the plan, the Ministry of Health (via the federal government) presented a preliminary vaccination plan[50,51].

The government of the state of São Paulo, whose measures have been supported by concurrent competence and the law to combat the new coronavirus, which grants local authorities the competence for emergency health actions (articles 3 and 7 of Law No. 13.979/2020)[21], launched its own vaccination plan on December 7, the São Paulo State Immunization Plan (PEI)[52].

Shortly after the state plan was presented, the federal government's planning, called the Brazilian Vaccination Plan[35] against COVID-19, was delivered to the STF (before the judgment of the unconstitutionality actions) and officially launched on December 16, 2020.

Despite the late elaboration of the national plan and the gaps in the information, its existence is necessary, as was the case with the campaign to combat influenza A H1N1.

Just for comparative analysis, the Ministry of Health, in 2009, through Technical Note No. 05/2010, introduced the influenza A H1N1 vaccination (declared a pandemic by the WHO)[53] in the official calendar. At that time, there was no objection from the federal government regarding vaccine planning. On the contrary, when introducing the new vaccine, it created a vaccination

strategy against the influenza virus, detailed the vaccination stages, clarified the provision for vaccine acquisition and guaranteed universal access to immunization/health (constitutional guarantee) through free vaccination in Basic Health Units (UBS) managed by SUS[54]. Vaccination of the influenza A H1N1 virus remains active and incorporated in the PNI and we believe, based on what we have studied, that this possibility cannot be ruled out in relation to vaccination against COVID-19.

With these two immunization plans presented, the PEI of the state of São Paulo[52] and the Brazilian Vaccination Plan[35] of the federal government, we have the following guidelines between the lines: in the first, the compulsory vaccination; in the second, the voluntariness of vaccination.

This diverse position portrays the total altercation and the truth in the dispute between the governor of the state of São Paulo and the president of the republic in the measurement of political forces. Apparently, the choice for compulsory vaccination is based on scientific evidence, while the voluntariness is supported by personal beliefs without scientific basis, such as the one that relates the use of the immunizer with the adverse effect of transforming the human being into a crocodile[55].

Immunization against COVID-19: the political question

Law No. 6,259, of October 30, 1975, provides for Epidemiological Surveillance actions, the PNI and the rules for compulsory notification of diseases, and clarifies that the Ministry of Health is responsible for coordinating actions related to the control of communicable diseases, provide guidance on Epidemiological Surveillance and the immunization program (article 1)[56].

By law, the Ministry of Health is responsible for preparing the PNI, which will define the strategy and coverage of vaccines, including mandatory vaccines (article 3, *caput* and sole paragraph). The PNI already exists[48] and has been in use in the country since 1975, therefore, at the moment, it is the role of the Ministry of Health to prepare the plan or technical strategy (by ordinance or technical note or technical report) that aims to incorporate the new immunization agents into the national program.

As noted in the legal text, the possibility of making certain vaccines compulsory is no longer new, and childhood vaccination included in the official PNI calendar is a typical example. In case of non-vaccination, the Statute of the Child and Adolescent (ECA) provides for the punishment of those responsible, parents, or tutors/guardians, whose duty is to take care of minors, guaranteeing their health, among other things. Mandatory vaccination, from the perspective of the ECA[57], has the purpose of preserving health (article 14), and that is exactly what the STF has just defined in topic 1103 of General Repercussion (leading case: ARE 1267879)[31,32,33]. Otherwise, it is also mandatory on certain international trips. The WHO advises that, if the country of destination requires it, it will be mandatory to present the International Certificate of Vaccination or Prophylaxis (ICVP). In these cases, the person can refuse, but will not be allowed to enter the country in question[58]. Even in Brazil, on some internal trips, depending on the region to be visited, vaccination is mandatory.

Still on the subject, the vaccines included in the Military Vaccination Calendar are mandatory for the immunization of the Armed Forces soldiers (article 1, sole paragraph of Normative Ordinance No. 94, of November 4, 2020), appearing as a necessary condition for enrollment in the courses provided for in the Armed Forces Teaching Systems and aptitude for Active Service on the occasion of health inspections (article 4)[59].

Thus, the compulsory nature of some vaccines is nothing new in the legal world, in society, and even in military life. Not being a measure separated from reality, already experienced by many, why would there be any hesitation about obligatoriness?

This article was written before the start of vaccination in the country, and, during the blind peer review process, the vaccination of the Brazilian population began.

In the first weeks, it was possible to observe the notorious adherence of people to the vaccination offered by the SUS, indicating that the compulsory vaccination against COVID-19, as well as the vaccination of children and adolescents, should more directly affect only that portion of the population that identifies with anti-vaccine movements or that refuse to recognize the safety and effectiveness of vaccines available for the new coronavirus, against all scientific evidence produced. The subject, however, deserves a separate study and complementary to the present one.

Lewandowski[31,32,33] explained it well, the 2020 pandemic revealed to Brazilians a new scenario in addition to a deadly virus. Not only does the virus victimize the population in terms of numbers of illnesses and deaths, but also the inconsistency of governance, which proved to be weak in the face of its responsibility to ensure the fundamental rights contemplated in articles 5, 6, and 196 of the CF. It is the responsibility of public agents to act strongly and effectively, through the implementation of policies or programs to combat COVID-19. And for such measures to be implemented, the moment requires the sum of actions with the union and joint planning of all government officials (federal government and federated entities). However, instead of the union of governmental forces, Brazil was invaded by polarization fueled by declarations and decisions of the federal government without scientific backing.

The discourse of radical positions – on the one hand, the president of the republic, and, on the other, the governor of the state of São Paulo – only results in negative consequences, to the point of disrespecting regulations and legal institutes[60].

The federal government, through the Ministry of Health, released a preliminary plan[50] shortly after presenting his defense in the action brought by the TCU[30] and, presented the "definitive" plan[35] when the deadline given by the STF in the unconstitutionality actions expired[31,32,33]. In the interval between one and the other plans of the Ministry of Health, the government of the state of São Paulo also presented a vaccination plan[52], this

one, however, at the state level. Notably, there is no consensus among the rulers.

Cooperation between federal entities with concurrent competence between the Union, the States, and the Federal District (constitutional norm - principle of cooperative federalism) should be followed in the search for the protection and defense of everyone's health, aiming at a single standardization (if not unique, at least harmonic and compatible with each other) to be instituted and respected in favor of the same objectives.

The federal government has the function of planning and promoting, on a permanent basis, the defense of all Brazilians and foreigners residing in the country against public calamities, defining and coordinating Epidemiological and Sanitary Surveillance systems and participating in the execution of Epidemiological Surveillance actions and other occurrences that may escape the control of the SUS state management or that represent a risk of national dissemination (joint reading of articles 21, XVIII and 198 of CF/88 and article 16, III, of Law No. 8.080/1990 and Legislative Decree No. 6/2020)[61,62].

On the other hand, it is not the role of the federal government to be guided by particular political or partisan and even ideological positions to reject or accept a particular vaccine and its inputs. The fight for vaccine A or vaccine B is not a governmental, federal, or state assignment.

It is possible to verify by the simple observation that the divergent positions of the government leaders cause uncertainty, distrust, and insecurity regarding the importance of vaccine immunization. The strategies of political agents during the health crisis influence the behavior and reactions of the population, including the perception of the government's effectiveness in dealing with the pandemic. The polarization of society is a reflection of these behaviors[63].

The particular reasons for opposing understandings about immunizers exposing in public discourse the rejection of one or some immunizers are not political attributions of the president of the republic nor of the governors.

Judging the efficient and effective immunizer is the responsibility of the scientific community and the competent state agencies, following the norms and principles of bioethics and the practices of evidence-based medicine.

Accepting and regulating the entry of the immunizer into the country is Anvisa's responsibility. On this subject, Normative Instruction No. 77, of November 17, 2020, provides for the procedure for the continuous submission of technical data for the registration of COVID-19 vaccines and establishes that the procedure is different for analyzing the data related to vaccines as they are generated and presented to the agency (Article 2, IV). After the continuous submission, with the conclusion and evaluation of quality, efficiency, and safety (these only reiterated by Anvisa), it will be possible to proceed with the formal registration at the agency (article 9, *caput*)[64].

Innovation in vaccine production technology is regulated by Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP). In Brazil, the regulatory agency that inspects compliance with good practices is Anvisa[65]. With this, the immunizing agents, complying with Anvisa's requirements and norms, will be able to enter the national territory, including for later commercialization.

It is worth clarifying that, exceptionally, Federal Law No. 13.979/2020 itself provides for the temporary authorization for the import and distribution of vaccine, without registration with Anvisa, provided that they are considered essential to help fight the new coronavirus pandemic and that they are registered at least by a foreign health authority (listed in the legal text - article 3, VIII)[21].

Thus, in a normal procedure, it is Anvisa's responsibility to resolve pending issues regarding the authorization protocols for vaccines against COVID-19 and, on the other hand, it is the responsibility of the federal government (or the state, according to legal permissions) to prepare the vaccination plan that integrates the existing PNI, acquire the immunizing agents and other necessary supplies and, finally, carry out the immunization. However, doubts remain about legitimate governance, whether federal or state.

By extrapolating or omitting their actions and competences, can governments delay vaccine planning and generate a feeling of insecurity in the population? The answer seems positive to us and the establishment of the so-called Parliamentary Commission of Inquiry on the Pandemic with the Federal Senate by determination of the STF (Writ of Mandamus No. 37.760/DF)[66], during the month of April 2021, while this material was being reviewed, it reveals the complexity in terms of agents and political interests involved in the State's actions in the face of the global health crisis and, in particular, in the conduct of the process of acquiring vaccines and immunization of the Brazilian population.

This population influenced (polarized)[60] by its rulers has been divided into demonstrations (mainly on social networks) pro and against the actions of the federal government and the compulsory vaccine, which refers to the memory of the Vaccine Revolt episode.

At the time, around the year 1904, there was a revolt of the population due to a law (headed by public health worker Oswaldo Cruz) that required vaccination against smallpox[67,68]. The campaign at that time, however, was carried out without proper information – a right that is now respected, consecrated, and monitored by the principles of transparency and information. The historical fact resulted in the non-submission of the population to mandatory vaccination and, until the end of the 1910s, the disease was present in the country, worth noting that its definitive (worldwide) eradication was only certified in 1979/80 by the WHO[69,70].

History sometimes repeats itself, we know, but what we want is the non-repetition of a movement (in that era social, now

political) that could get in the way of the right decisions to face COVID-19.

Vaccination is the right measure, in light of the scientific evidence gathered so far. Scientific knowledge is validated by the method it uses to seek answers, and the law has adopted scientific grounds as a criterion for governmental decision. Not politicizing vaccination is the solution to achieving the right measure and most of the Brazilian population, it seems, understood the need for vaccination in the fight against COVID-19.

CONCLUSIONS

The right to health in Brazil encompasses actions and services to prevent diseases and health problems. The 1988 CF enshrines health (and immunization) as a right to be guaranteed by the State, available to all through the SUS.

The right to vaccination has been implemented by the PNI, which makes vaccines available to the population in greater numbers than those recommended by the WHO. The achievement of adherence to the vaccination plan and the culture of immunization occurred over many years, along a trajectory of health policies that began to guarantee the population adequate information and safety of the immunizers offered by the Ministry of Health.

Placing this health achievement in the midst of political disputes gives rise to distrust regarding the safety and efficacy of the PNI and COVID-19 vaccines. It results, once again, in a process of public disinformation and, in this case, still fueled by statements by political agents, without any backing in scientific evidence.

It doesn't matter who will win the vaccine race, whether the federal government or the São Paulo government, nor who will electorally profit from it, what matters is that this political dispute does not harm the Brazilian population, especially in view of the need for normative decisions by government officials (president, governors, and mayors) in favor of compulsory vaccination, whose legitimacy has proved to be possible, with safe and effective immunizers, such as those approved by the competent state agencies.

REFERENCES

1. Lai CC, Shin TP, Ko W, Tang HJ, Hsueh PR. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease-2019 (COVID-19): the epidemic and the challenges. Int J Antimicrob Agents. 2020;55(3):1-9. https://doi.org/10.1016/j.ijantimicag.2020.105924
2. Pan American Health Organization – PAHO. Folha informativa: COVID-19 (doença causada pelo novo coronavírus). Washington: Pan American Health Organization; 2020[acesso 28 nov 2020]. Disponível em: https://www.paho.org/bra/index.php?option=com_content&view=article&id=6101:covid19&Itemid=875
3. World Health Organization – WHO. WHO director-general's opening remarks at the media briefing on COVID-19. Speeches. 11 mar 2020[acesso 26 nov 2020]. Disponível em: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020
4. Johns Hopkins University – JHU. COVID-19 dashboard by the center for systems science and engineering (CSSE). Baltimore: Johns Hopkins University; 2021[acesso 7 jan 2021]. Disponível em: https://coronavirus.jhu.edu/map.html
5. Ministério da Saúde (BR). Boletim coronavírus. Brasília: Ministério da Saúde; 2021[acesso 6 jan 2021]. Disponível em: https://www.coronavirus.ms.gov.br/?cat=5
6. Worldmeter. World population. Pudong: Dadax; 2021[acesso 7 jan 2021]. Disponível em: https://www.worldometers.info/world-population/
7. Worldmeter. Population by country. Pudong: Dadax; 2021[acesso 7 jan 2021]. Disponível em: https://www.worldometers.info/world-population/population-by-country/
8. Pan American Health Organization – PAHO. Folha informativa COVID-19: escritório da OPAS e da OMS no Brasil. Washington: Pan American Health Organization; 2020[acesso 15 dez 2020]. Disponível em: https://www.paho.org/pt/covid19
9. World Health Organization – WHO. Coronavirus disease (COVID-19): vaccines. Geneva: 2020[acesso 14 dez 2020]. Disponível em: https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines?adgroupsurvey={adgroupsurvey}&gclid=Cj0KCQiA2uH-BRCCARIsAEeef3k7Uw3aeGANKnDa9xk0FmrTZEPteigPjvc688gOEInLll6X_EqkfhAaArxqEALw_wcB
10. World Health Organization – WHO. Countries. Geneva: 2020[acesso 26 nov 2020]. Disponível em: https://www.who.int/countries/
11. Instituto Butantan. Vacina do Butantan chega à fase final. Notícias. 23 nov 2020[acesso 11 dez 2020]. Disponível em: https://butantan.gov.br/noticias/vacina-do-butantan-chega-a-fase-final
12. Fundação Oswaldo Cruz – Fiocruz. Como é feita a vacina candidata da COVID-19 da Universidade de Oxford/AstraZeneca? Rio de Janeiro: Fundação Oswaldo Cruz; 2020[acesso 11 dez 2020]. Disponível em: https://portal.fiocruz.br/pergunta/como-e-feita-vacina-candidata-da-covid-19-da-universidade-de-oxford/astrazeneca
13. Fundação Oswaldo Cruz – Fiocruz. Vacinas contra COVID-19. Rio de Janeiro: Fundação Oswaldo Cruz; 2020[acesso 11 dez 2020]. Disponível em: https://portal.fiocruz.br/vacina-covid-19-ensaios-clinicos
14. Agência Nacional de Vigilância Sanitária – Anvisa. Vacinas COVID-19: fique por dentro do mapa das vacinas em teste no Brasil. Notícias. 14 set 2020[acesso 5 dez 2020]. Disponível em: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2020/fique-por-dentro-do-mapa-das-vacinas-em-teste-no-brasil

15. Pan American Health Organization – PAHO. Regulamento sanitário internacional (RSI). Washington: Pan American Health Organization; 2020[acesso 27 nov 2020]. Disponível em: https://www.paho.org/bra/index.php?option=com_content&view=article&id=5847:regulamento-sanitario-internacional-rsi&Itemid=812
16. Brasil. Decreto Nº 395, de 9 de julho de 2009. Aprova o texto revisado do regulamento sanitário internacional, acordado na 58ª Assembléia Geral da Organização Mundial de Saúde, em 23 de maio de 2005. Diário Oficial União. 10 jul 2009.
17. Brasil. Decreto Nº 10.212, de 30 de janeiro de 2020. Promulga o texto revisado do regulamento sanitário internacional, acordado na 58ª Assembleia Geral da Organização Mundial de Saúde, em 23 de maio de 2005. Diário Oficial União. 31 jan 2020.
18. Câmara dos Deputados Federais. Projeto de lei Nº 9, de 3 de fevereiro de 2020. Dispõe sobre as medidas para enfrentamento da emergência de saúde pública de importância internacional decorrente do coronavírus. Proposições Web. 3 fev 2020[acesso 26 nov 2020]. Disponível em: https://www.camara.leg.br/proposicoesWeb/ prop_mostrarintegra;jsessionid=E5D34B26717B978E92D944DF0FA5AB69.proposicoesWebExterno1?codteor=1853941&filename=PL+23/2020
19. Câmara dos Deputados Federais. Projeto de lei Nº 23, de 4 fevereiro de 2020. Dispõe sobre as medidas para enfrentamento da emergência de saúde pública de importância internacional decorrente do coronavírus responsável pelo surto de 2019. Proposições Web. 4 fev 2020[acesso 26 nov 2020]. Disponível em: https://www.camara.leg.br/proposicoesWeb/fichadetramitacao?idProposicao=2236343
20. Brasil. Projeto de lei Nº 23, de 5 fevereiro de 2020. Dispõe sobre as medidas para enfrentamento da emergência de saúde pública de importância internacional decorrente do coronavírus responsável pelo surto de 2019. Atividade Legistativa. 5 fev 2020[acesso 26 nov 2020]. Disponível em: https://www25.senado.leg.br/web/atividade/materias/-/materia/140490
21. Brasil, Lei Nº 13.979, de 6 de fevereiro de 2020. Dispõe sobre as medidas para enfrentamento da emergência de saúde pública de importância internacional decorrente do coronavírus responsável pelo surto de 2019. Diário Oficial União. 7 fev 2020.
22. Brasil. Decreto de 16 de abril de 2020. Exoneração Luiz Henrique Mandetta do cargo de Ministro da Saúde. Diário Oficial União. 17 abr 2020.
23. Conselho Nacional de Secretarias Municipais da Saúde – CONASEMS. Nelson Teich é nomeado novo Ministro da Saúde. Notícias. 16 abr 2020[acesso 27 nov 2020]. Disponível em: https://www.conasems.org.br/nelson-teich-e-nomeado-para-ministro-da-saude/
24. British Broadcast Company – BBC. Ministro da Saúde Nelson Teich pede demissão menos de um mês depois de assumir. BBC News. 15 maio 2020[acesso 27 nov 2020]. Disponível em: https://www.bbc.com/portuguese/brasil-52683285
25. Pedrozo J. Pazuello é nomeado oficialmente como ministro da Saúde interino. Gazeta do Povo. 3 jun 2020[acesso 28 nov 2020]. Disponível em: https://www.gazetadopovo.com.br/republica/breves/pazuello-ministro-da-saude-interino/
26. Redação. Pazuello tomará posse na quarta como ministro da Saúde após período como interino. IstoÉ. 14 set 2020[acesso 29 nov 2020]. Disponível em: https://istoe.com.br/pazuello-tomara-posse-na-quarta-como-ministro-da-saude-apos-periodo-como-interino/
27. Verdélio A. Ministério da Saúde muda formato de divulgação de dados de COVID-19. Agência Brasil. 8 jun 2020[acesso 28 dez 2020]. Disponível em: https://agenciabrasil.ebc.com.br/saude/noticia/2020-06/ministerio-da-saude-muda-formato-de-divulgacao-de-dados-de-covid-19
28. Universo OnLine – UOL. MP dá 72h para Ministério da Saúde explicar mudança na divulgação de mortes. UOL Coronavírus. 6 jun 2020[acesso 30 dez 2020]. Disponível em: https://noticias.uol.com.br/saude/ultimas-noticias/redacao/2020/06/06/mp-da-72h-para-ministerio-da-saude-explicar-mudanca-na-divulgacao-de-mortes.htm?cmpid=copiaecola
29. Parreira M, Rodrigues M. Governo obedece à ordem do STF, e Ministério da Saúde volta a divulgar dados completos da COVID. G1 Política. 9 jun 2020[acesso 30 dez 2020]. Disponível em: https://g1.globo.com/politica/noticia/2020/06/09/ministerio-da-saude-volta-a-divulgar-no-site-oficial-dados-acumulados-da-covid-19.ghtml
30. Secom TCU. TCU determina à Casa Civil que elabore plano de imunização do Brasil. Notícias. 21 ago 2020[acesso em 30 nov 2020] Disponível em: https://portal.tcu.gov.br/imprensa/noticias/tcu-determina-a-casa-civil-que-elabore-plano-de-imunizacao-do-brasil.htm
31. Lewandowski R. Ação direita de inconstitucionalidade Nº 6.586 Distrito Federal. Brasília: Supremo Tribunal Federal; 2020[acesso 28 dez 2020]. Disponível em: http://www.stf.jus.br/arquivo/cms/noticiaNoticiaStf/anexo/adi6586despacho.pdf
32. Lewandowski R. Ação direita de inconstitucionalidade Nº 6.587 Distrito Federal. Brasília: Supremo Tribunal Federal; 2020[acesso 29 dez 2020]. Disponível em: http://www.stf.jus.br/arquivo/cms/noticiaNoticiaStf/anexo/adi6587despacho.pdf
33. Supremo Tribunal Federal – STF. Ministro Lewandowski pede informações ao presidente da República sobre vacinação. Notícias. 23 out 2020[acesso 30 nov 2020]. Disponível em: http://www.stf.jus.br/portal/cms/verNoticiaDetalhe.asp?idConteudo=453974
34. Valente F. Para Lewandowski, União tem o dever de usar vacinas contra a COVID-19. Boletim de Notícias Conjur. 24 nov 2020[acesso 26 nov 2020]. Disponível em: https://www.conjur.com.br/2020-nov-24/lewandowski-uniao-dever-usar-vacinas-covid

35. Ministério da Saúde (BR). Plano nacional de operacionalização da vacinação contra a COVID-19. Brasília: Ministério da Saúde; 2020[acesso 12 dez 2020]. Disponível em: https://download.uol.com.br/files/2020/12/89110721 5_2020_12_11_plano_de_vacinacao_covid19__revisado.pdf
36. Barroso R. Possibilidade dos pais deixarem de vacinar os seus filhos, tendo como fundamento convicções filosóficas, religiosas, morais e existenciais. Brasília: Supremo Tribunal Federal; 2020[acesso 2 jan 2020]. Disponível em: http://www.stf.jus.br/portal/ jurisprudenciaRepercussao/verAndamento Processo.asp?incidente=5909870&numero Processo=1267879&classeProcesso= ARE&numeroTema=1103
37. Limal YOR, Costal EA. Regulamento sanitário internacional: emergências em saúde pública, medidas restritivas de liberdade e liberdades individuais. Vigil Sanit Debate. 2015;3(1):10-18. https://doi.org/10.3395/2317-269x.00266
38. Kant I. Metafísica dos costumes: introdução à doutrina da virtude. São Paulo: Edipro; 2012.
39. Gavião Filho AP. Colisão de direitos fundamentais, argumentação e ponderação. Porto Alegre: Advogado; 2011.
40. Abud CO, Souza LP. Uso obrigatório de máscara facial para conter a COVID-19 no Brasil: limitação legítima ao direito fundamental de autodeterminação. Vigil Sanit Debate. 2020;8(3):34-43. https://doi.org/10.22239/2317-269x.01651
41. Canotilho JJG. Direito constitucional e teoria da constituição. 7a ed. Coimbra: Almedina; 2003.
42. Rezek CN. O princípio da proporcionalidade no estado democrático de direito. São Paulo: Lemos & Cruz; 2004.
43. Santos HS. Vacinas. Goiânia: Biologia Net; 2020[acesso 1 dez 2020]. Disponível em: https://www.biologianet.com/ saude-bem-estar/vacinas.htm
44. Souza MTNF, Camargos KCO, Guimarães MR, Neves MRO, Alves CF. Impactos da hesitação vacinal na epidemiologia do sarampo. Brazil J Health Rev. 2020;3(2):1-3. https://doi.org/10.34119/bjhrv3n4-100
45. Campos AL. Uma análise bioética das decisões judiciais brasileiras sobre os eventos adversos pós-vacinação [tese]. Brasília: Universidade de Brasília; 2017[acesso 30 nov 2020]. Disponível em https://repositorio.unb.br/ handle/10482/23893
46. Ministério da Saúde (BR). Programa Nacional de Imunizações. Brasília: Ministério da Saúde; 2020[acesso 7 dez 2020]. Disponível em: https://portalarquivos.saude. gov.br/campanhas/pni/
47. Sociedade Brasileira de Imunizações – SBIM. Calendários de vacinação. Calendário SBIM. 27 nov. 2020[acesso 30 nov 2020]. Disponível em: https://sbim.org.br/ calendarios-de-vacinacao
48. Bordinhão R. O programa nacional de imunização brasileiro frente aos desafios para sua modernização e evolução. 24+Farma. 2020[acesso 2 dez 2020]. Disponível em: https://www.doisamaisfarma.com.br/noticias/o-p rograma-nacional-de-imunizacao-brasileiro-frente-aos -desafios-para-sua-modernizacao-e-evolucao/
49. Redação. No Roda Viva, especialistas esclarecem dúvidas sobre as vacinas contra a COVID-19. TV Cultura Notícias. 15 dez 2020[acesso 18 dez 2020]. Disponível em: https://cultura.uol.com.br/noticias/14823_no-roda-viva-e specialistas-esclarecem-duvidas-sobre-as-vacinas-contra-a-covid-19-assista.html
50. Fundação Oswaldo Cruz – Fiocruz. Plano preliminar de vacinação contra a COVID-19 prevê quatro fases. Notícias e Artigos. 2 dez 2020 [acesso 4 dez 2020]. Disponível em: https://www.bio.fiocruz.br/index. php/br/noticias/2090-plano-preliminar-de-vacinac ao-contra-a-covid-19-preve-quatro-fases
51. Associação Nacional de Especialistas em Políticas Publicas e Gestão Governamental - ANESP. Ex-ministros da saúde pedem: vacina para todos já! Notícias. 9 dez 2020[acesso 12 dez 2020]. Disponível em: http://anesp.org.br/ todas-as-noticias/vacina-para-todos-ja
52. Governo do Estado de São Paulo. Governo de SP inicia vacinação contra coronavírus em 25 de janeiro. Notícias Coronavírus. 7 dez 2020[acesso 8 dez 2020]. Disponível em: https://www.saopaulo.sp.gov.br/ noticias-coronavirus/governo-de-sp-inicia-vacinacao-con tra-coronavirus-em-25-de-janeiro/
53. Ministério da Saúde (BR). Informe técnico operacional: estratégia de vacinação contra o vírus de influenza pandêmico (H1N1) 2009. Brasília: Ministério da Saúde; 2010[acesso 29 nov 2020]. Disponível em: http://bvsms. saude.gov.br/bvs/publicacoes/estrategia_nacional_ vacinacao_influenza.pdf
54. Ministério da Saúde (BR). Estratégia de vacinação contra o vírus de influenza A H1N1. Brasília: Ministério da Saúde; 2010[acesso 29 nov 2020]. Disponível em: https://www. medicinanet.com.br/conteudos/revisoes/3005/nota_ tecnica__estrategia_de_vacinacao_contra_o_virus_de_ influenza_ah1n1.htm
55. Universo OnLine – UOL. Bolsonaro: se tomar vacina e virar jacaré não tenho nada a ver com isso. UOL Vídeos. 17 dez 2020[acesso 30 dez 2020]. Disponível em: https://www.youtube.com/watch?v=lBCXkVOEH-8
56. Brasil. Lei Nº 6.259, de 30 de outubro de 1975. Dispõe sobre a organização das ações de vigilância epidemiológica, sobre o programa nacional de imunizações, estabelece normas relativas à notificação compulsória de doenças, e dá outras providências. Diário Oficial União. 31 out 1975.
57. Lamy M, Abud CO, Ferreira MR. Vacinação infantil: autonomia da vontade x dever familiar. An Enc Nac Pós Grad. 2019;3(1):1-3.
58. Brasil. Tirar o certificado internacional de vacinação. Brasília: Saúde e Vigilância Sanitária; 2020[acesso 8 dez 2020]. Disponível em: https://www.gov.br/pt-br/servicos/ obter-o-certificado-internacional-de-vacinacao-e-profilaxia
59. Ministério da Defesa. Portaria normativa Nº 94, de 4 de novembro de 2020. Institui o calendário de vacinação militar. Diário Oficial União. 5 nov 2020.
60. Moraes E. COVID-19 e a epidemias da polarização. Linguasagem. 2020;35(1):1-21.

61. Brasil. Decreto legislativo Nº 6, de 18 de março de 2020. Reconhece, para os fins do art. 65 da lei complementar Nº 101, de 4 de maio de 2000, a ocorrência do estado de calamidade pública, nos termos da solicitação do presidente da república encaminhada por meio da mensagem Nº 93, de 18 de março de 2020. Diário Oficial União. 20 mar 2019.

62. Brasil. Lei Nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Diário Oficial União. 20 set 1990.

63. Sobral F, Carvalho J, Tagowska U, Furtado LMGP, Grobman M. Melhor prevenir do que remediar: o *sensemaking* da liderança nos tempos da COVID-19. Rev Adm Pública. 2020;54(4):1-24. https://doi.org/10.1590/0034-761220200262x

64. Ministério da Saúde (BR). Instrução normativa Nº 77, de 17 de novembro de 2020. Dispõe sobre o procedimento de submissão contínua de dados técnicos para o registro de vacinas COVID-19. Diário Oficial União. 18 nov 2020.

65. Agência Nacional de Vigilância Sanitária – Anvisa. Entenda a certificação em boas práticas de fabricação. Brasília: Agência Nacional de Vigilância Sanitária; 2020[acesso 29 nov 2020]. Disponível em: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2020/entenda-a-certificacao-em-boas-praticas-de-fabricacao

66. Barroso R. Mandado de segurança Nº 37.760 do Distrito Federal. Brasília: Supremo Tribunal Federal; 2021[acesso 18 jun 2021]. Disponível em: http://portal.stf.jus.br/processos/detalhe.asp?incidente=6129512

67. Hochman G. Vacinação, varíola e uma cultura da imunização no Brasil. Cienc Saúde Coletiva. 2011;16(2):375-85. https://doi.org/10.1590/S1413-81232011000200002

68. Homma A, Martins RM, Leal MLF, Freire MS, Couto AR. Atualização em vacinas, imunizações e inovação tecnológica. Cienc Saúde Coletiva. 2011;16(2):445-58. https://doi.org/10.1590/S1413-81232011000200008

69. Pan American Health Organization – PAHO. Erradicação da varíola: um legado de esperança para COVID-19 e outras doenças. Washington: Pan American Health Organization; 2020[acesso 1 dez 2020]. Disponível em: https://www.paho.org/bra/index.php?option=com_content&view=article&id=6165:erradicacao-da-variola-um-legado-de-esperanca-para-covid-19-e-outras-doencas&Itemid=812#:~:text=8%20de%20maio%20de%202020,pessoas%20somente%20no%20s%C3%A9culo%20XX.

70. Fundação Oswaldo Cruz – Fiocruz. Varíola: 40 anos do certificado de erradicação. Notícias e Artigos. 10 dez 2019[acesso 6 dez 2020]. Disponível em: https://www.bio.fiocruz.br/index.php/br/noticias/1709-variola-40-anos-do-certificado-de-erradicacao#:~:text=Baseado%20no%20sucesso%20obtido%20na,no%20pa%C3%ADs%2C%20certificada%20em%201977

Author's Contributions

Abud CO, Souza LP - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. The authors approved the final version of the work.

Conflict of Interests

The authors inform that there is no potential conflict of interest with peers and institutions, politicians, or financial in this study.